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10/593,842	07/10/2007	Yusuke Nakamura	082368-000510US	3233

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EXAMINER	
WHITEMAN, BRIAN A	
ART UNIT	PAPER NUMBER
1635	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/593,842	NAKAMURA ET AL.	
	Examiner	Art Unit	
	Brian Whiteman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11/26/08,1/12/09*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-68* is/are pending in the application.

4a) Of the above claim(s) *1-43 and 62-68* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *44-46,48-56,59,60* is/are rejected.

7)☒ Claim(s) *47,57,58 and 61* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 September 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/27/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group 22 (claims 44-61), SEQ ID NO: 34 and KIF1 in the reply filed on 11/26/08 and 1/12/09 is acknowledged. The traversal is on the ground(s) that unity of invention exists for SEQ ID NOs: 32-34 (See MPEP 1850). This is not found persuasive because the special technical feature for the products is the composition in claim 59. The composition in claim 59 is taught by the prior art (see pages 10 and 11 of the election/restriction). In addition, the special technical feature of SEQ ID NOs: 32-34 is siRNA targeting KIF11. The prior art teaches siRNA targeting the KIF11 gene (Jackson et al., US 20080234941). Thus, the inventions in the present application do not contain a single inventive concept. Furthermore, there is more than one nucleotide sequence recited in the instant claims. The Office decision to rescind the 1996 waiver (for examining up to 10 dependent and distinct nucleotide sequences) is based upon the increasing computational, search and examination burden required for the consideration of nucleic acids sequences, and complexity of claims drawn to such, compared to the time of the 1996 waiver. See http://www.uspto.gov/web/patents/patog/week13/OG/TOC.htm#ref14.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-43 and 62-68, GHSR1b, NTSR1 and FOXM1 in claims 44, 45, 46, 47, 59, 60, 62 and SEQ ID NOs: 3, 5, 33-37, 106 and 108 in claims 45, 46, 47, and 61 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a

nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 11/26/08 and 1/12/09.

The examiner has considered the international search report.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 45, 46, and 49-53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term “at least about 10 contiguous” in claim 45 and the term ‘from about 19’ in claim 46 are relative terms which renders the claims indefinite. The terms are not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The metes and bounds of the term are undefined since it is defined whether the term is limited to ‘at least 10 or about 10’ or ‘from 19 or about 19’.

The term “less than about 100(75, 50, 25, 19)” in claims 49-53 is a relative term which renders the claims indefinite. The term " less than about 100(75, 50, 25, 19)" is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The metes and bounds of the term are

undefined since it is defined whether the term is limited to 'less than 100(75, 50, 25, 19)' or about 100(75, 50, 25, 19)'.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 44, 48-56, and 59-60 are rejected under 35 U.S.C. 102(e) as being anticipated by Jackson et al. (US 2008/0234941).

With respect to the intended use in claims 59 and 60, the intended use does not have patentable weight over a product taught in the prior art with the same structural limitations recited in the claimed product. In order to constitute anticipatory prior art, a reference must identically disclose the claimed compound, but no utility need be disclosed by the reference. In re Schoenwald, 964 F.2d 1122, 22 USPQ2d 1671 (Fed. Cir. 1992).

Jackson et al. teach siRNA targeting KIF11 (page 40, Table 3). Jackson teaches that the siRNA can be used to construct vectors, including shRNA vectors (paragraphs 0274 and 0290).

Claims 44, 49-53, and 59-60 are rejected under 35 U.S.C. 102(e) as being anticipated by Jakobovits et al. (US 7,358,353).

With respect to the intended use in claims 59 and 60, the intended use does not have patentable weight over a product taught in the prior art with the same structural limitations recited in the claimed product. See In re Schoenwald, 964 F.2d 1122, 22 USPQ2d 1671 (Fed. Cir. 1992).

Jakobovits et al. teach siRNA targeting EG5, also known as KIF11 (column 140).

Claims 44, 48-56, and 59-60 are rejected under 35 U.S.C. 102(e) as being anticipated by Khvorova et al. (US 2005/0245475).

With respect to the intended use in claims 59 and 60, the intended use does not have patentable weight over a product taught in the prior art with the same structural limitations recited in the claimed product. In re Schoenwald, 964 F.2d 1122, 22 USPQ2d 1671 (Fed. Cir. 1992).

Khvorova et al. teach siRNA targeting KIF11 (paragraph 0092 and Figure 12). Khvorova teaches that the siRNA can be used to construct vectors, including shRNA vectors (paragraphs 0109 and 0116).

Claims 44, 49-53, and 59-60 are rejected under 35 U.S.C. 102(b) as being anticipated by Weil et al. (Biotechniques 33:1244-48, 2002, of record). With respect to the intended use in claims 59 and 60, the intended use does not have patentable weight

over a product taught in the prior art with the same structural limitations recited in the claimed product. In re Schoenwald, 964 F.2d 1122, 22 USPQ2d 1671 (Fed. Cir. 1992).

Weil et al. teach siRNA targeting Eg5, also known as KIF11 (pages 1244-45).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 44-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wood et al. (US 6,414,121) taken with Tuschl (The siRNA user guide, 2001) in further view of Khvorova et al. (US 2007/0031844). Wood et al. teach antisense molecules targeting kinesin KSP and kinesin KSP being involved in cellular proliferation in cancer (abstract and columns 3-4). Wood et al. further teach a kinesin KSP nucleic acid comprising SEQ ID NO: 34 (SEQ ID NO: 7). However, Wood et al. do not specifically teach double stranded molecule comprising a nucleotide comprising at least 10 contiguous nucleotides from the nucleotide sequence of SEQ ID NO: 1. NOTE: SEQ ID NO: 1 comprises SEQ ID NO: 34.

Tuschl et al. teach a dsRNA design tool and guidelines for dsRNA design to generate a report indicating preferential sense and antisense dsRNA oligonucleotides for a given mRNA sequence. In addition, Khvorova et al. teach a method of producing and screening dsRNA molecules that successfully inhibit a target sequence (abstract and pages 96-99). Furthermore, Khvorova et al. teach that one of ordinary skill in the art using Tuschl's protocol would successfully produce dsRNA molecules that inhibits a target sequence (page 4 of provisional 60/502,050 cited on 20070031844).

It would have been obvious to utilize a dsRNA molecule, as taught by Wood, Khvorova, and Tuschl to study inhibition of kinesin KSP in cells and to design the dsRNA using the guidelines targeted to a kinesin KSP gene.

One of ordinary skill in the art would have been motivated to study kinesin KSP expression in cancer cells via inhibiting kinesin KSP with a dsRNA because Wood et al. teach the kinesin KSP nucleic acid and the up-regulation of this gene (columns 3-4) and Khvorova teach that dsRNA molecules are preferential inhibitory molecules; achieve the product because Tuschl and Khvorova teach guidelines, wherein insertion of the kinesin KSP sequence taught by Wood et al. results in the identification of hotspots and preferential dsRNA sequences and specifically identified a sequence that is identical to a preferred sense strand of a dsRNA molecule.

"The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." See ***KSR v. Teleflex***, 550 U.S. ___, 127 S. Ct. 1727 (2007).

Since it was known that kinesin KSP expression is upregulated in cancer cells, as evidenced by Wood et al., one of ordinary skill in the art would have been motivated to study the inhibition of kinesin KSP expression. Furthermore, one of ordinary skill in the art would have been motivated to insert the known kinesin KSP sequence into publicly accessible siRNA user guidelines to determine preferred dsRNA molecules specific for kinesin KSP, as it was known that dsRNA molecules were preferential inhibitory molecules, as evidenced by Tuschl and Khvorova.

Finally, one of ordinary skill in the art would have had a reasonable expectation of success at generating dsRNA molecules because Tuschl et al. taken with Khvorova teach a method of designing a dsRNA and in view of the guidelines it would generate

the instant dsRNA molecules as preferable sense to use to target the kinesin KSP target sequence.

Thus, in the absence of evidence to the contrary, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

Claims 47, 57, 58, and 61 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number 571-272-0764. The examiner can normally be reached on from 6:30 to 4:00 (Eastern Standard Time). The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor James Douglas Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Brian Whiteman/
Primary Examiner, Art Unit 1635